


DECLARATION OF CONFORMITY			
Product Name: Post-Op Bra, Bianca		Product no.: 3211	
APPROVED BY TYTEX		APPROVED BY CUSTOMER	VALID FROM 04. May 2021
		VERSION NO. 1.1	

DECLARATION OF CONFORMITY

According to Regulation 2017/745 on Medical Devices (MDR), Tytex A/S hereby declares to fulfil all relevant requirements for the below mention products as set out in Annex I General safety and performance requirements, Annex II Technical documentation, Annex III Technical documentation on post-market surveillance and Annex XIV Clinical evaluation and post-market follow-up.


The Post-Op Bra, Bianca are class I, rule I, non-sterile CE marked products intended for fixation of a bandage or another medical device for post-surgical use and for comfortable wear for a maximum of wound and scar protection.

SRN: DK-MF-000003620

Brand: CareFix

Product number	Product name	Size	Colour	Basic UDI-DI
3211 61-01	Post-Op Bra, Bianca	S	White	57039361265170ABJ4
3211 61-03	Post-Op Bra, Bianca	M	White	57039361265170ABJ4
3211 61-05	Post-Op Bra, Bianca	L	White	57039361265170ABJ4
3211 61-07	Post-Op Bra, Bianca	XL	White	57039361265170ABJ4
3211 61-09	Post-Op Bra, Bianca	2XL	White	57039361265170ABJ4
3211 61-11	Post-Op Bra, Bianca	3XL	White	57039361265170ABJ4
3211 62-01	Post-Op Bra, Bianca	S	Black	57039361265170ABJ4
3211 62-03	Post-Op Bra, Bianca	M	Black	57039361265170ABJ4
3211 62-05	Post-Op Bra, Bianca	L	Black	57039361265170ABJ4
3211 62-07	Post-Op Bra, Bianca	XL	Black	57039361265170ABJ4
3211 62-09	Post-Op Bra, Bianca	2XL	Black	57039361265170ABJ4
3211 62-11	Post-Op Bra, Bianca	3XL	Black	57039361265170ABJ4

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This declaration is issued under the sole responsibility of Tytex A/S



Kim Remin Ankjaer
VP of Quality & Environment
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TYTEX

MAKING HEALTHCARE MORE HUMAN

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